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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 9517**  
Tsuyoshi SUZUKI et al. : Docket No. 2004\_1909A  
Serial No. 10/516,360 ✓ : Group Art Unit 1614  
Filed March 4, 2005 : Examiner **Not Yet Assigned**

PREVENTIVES AND/OR REMEDIES FOR  
SUBJECTS WITH THE EXPRESSION OR  
ACTIVATION OF Her2 AND/OR EGFR

**INFORMATION DISCLOSURE STATEMENT**

THE COMMISSIONER IS AUTHORIZED  
TO CHARGE ANY DEFICIENCY IN THE  
FEES FOR THIS PAPER TO DEPOSIT  
ACCOUNT NO. 23-0975

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the references listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☐ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application PCT/\_\_\_\_\_; and/or
- ☐ each reference previously cited in prior parent application Serial No. \_\_\_\_\_.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, or

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

**and thus no certification and/or fee is required.**

1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

**the certification of paragraph 2 below is provided, and**

**the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.**

2. It is hereby certified

- a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
- b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.
4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
  - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
  - c. ☐ the concise explanation contained in the specification of the present application at page,
  - d. ☐ the concise explanation set forth in the attached English language abstract,
  - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.
6. ☐ Statement Under 37 CFR 1.704(d)

Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Tsuyoshi SUZUKI et al.

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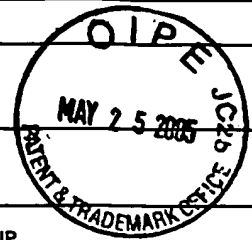
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May 25, 2005

## INFORMATION DISCLOSURE STATEMENT

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)  
(Use several sheets if necessary)

Date Submitted to PTO: May 25, 2005

ATTY DOCKET NO.  
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10/516,360APPLICANT  
Tsuyoshi SUZUKI et al.FILING DATE  
March 4, 2005GROUP  
1614

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AB						

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AC	K. Yoshida et al., Expression of growth factors and their receptors in human esophageal carcinomas: regulation of expression by epidermal growth factor and transforming growth factor $\alpha$ , J. Cancer Res. Clin. Oncol., Vol. 119, pp. 401-407, 1993.
	AD	V. Rusch et al., "Differential Expression of the Epidermal Growth Factor Receptor and its Ligands in Primary Non-Small Cell Lung Cancers and Adjacent Benign Lung", Cancer Research, Vol. 53, pp. 2379-2385, May 15, 1993.
	AE	L. Frederick et al., "Diversity and Frequency of Epidermal Growth Factor Receptor Mutations in Human Glioblastomas", Cancer Research, Vol. 60, pp. 1383-1387, March 1, 2000.
	AF	R. Seshadri et al., "Clinical Significance of HER-2/ <i>neu</i> Oncogene Amplification in Primary Breast Cancer", Journal of Clinical Oncology, Vol. 11, No. 10, pp. 1936-1942, October 1993.
	AG	A. Berchuck et al., "Overexpression of HER-2/ <i>neu</i> is Associated with Poor Survival in Advanced Epithelial Ovarian Cancer", Cancer Research, Vol. 50, pp. 4087-4091, July 1, 1990.
	AH	I. Osman et al., "Her-2/ <i>neu</i> (P185 <i>neu</i> ) Protein Expression in the Natural or Treated History of Prostate Cancer", Clinical Cancer Research, Vol. 7, pp. 2643-2647, September 2001.
	AI	C. L. Arteaga, "The Epidermal Growth Factor Receptor: From Mutant Oncogene in Nonhuman Cancers to Therapeutic Target in Human Neoplasia", Journal of Clinical Oncology, Vol. 19, No. 18s, pp. 32s-40s, September 15, 2001.
	AJ	Y. Kokai et al., "Synergistic Interaction of p185c- <i>neu</i> and the EGF Receptor Leads to Transformation of Rodent Fibroblasts", Cell, Vol. 58, pp. 287-292, July 28, 1989.
	AK	W. Xia et al., "Combination of EGFR, HER-2/ <i>neu</i> , and HER-3 is a Stronger Predictor for the Outcome of Oral Squamous Cell Carcinoma than any Individual Family Members", Clinical Cancer Research, Vol. 5, pp. 4164-4174, December 1999.

EXAMINER

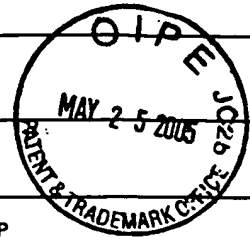
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## FOREIGN PATENT DOCUMENTS

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	BB						
	BC						
	BD						

## OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	BE	N. S. Soukos et al., "Epidermal Growth Factor Receptor-Targeted Immunophotodiagnosis and Photoimmunotherapy of Oral Precancer <i>In Vivo</i> ", Cancer Research, Vol. 61, pp. 4490-4496, June 1, 2001.					
	BF	T. Petit et al., "Chemotherapy Response of Breast Cancer Depends on HER-2 Status and Anthracycline dose Intensity in the Neoadjuvant Setting", Clinical Cancer Research, Vol. 7, pp. 1577-1581, June 2001.					
	BG	J. Baselga et al., "Initial Results from a Phase II Trial of ZD1839 (IRESSA) as Second- and Third-Line Monotherapy for Patients with Advanced Non-Small-Cell Lung Cancer (IDEAL 1)", Clinical Cancer Res., Vol. 7, #630A, p. 3780s, 2001.					
	BH	Okamoto et al., "Journal of Japan Society of Clinical Oncology, Vol. 35, No. 2, 340 (P-87), September 20, 2000.					
	BI						

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